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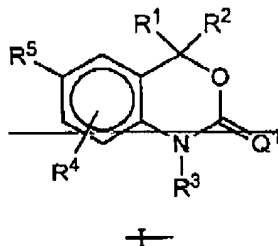
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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1(Currently Amended). A method of inducing contraception comprising the step of delivering to a female of child-bearing age a composition comprising a compound of formula I or formula II, or a tautomer thereof, in a regimen which involves delivering a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to said female, wherein formula I or II is:



wherein:

~~R¹ and R² are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₂ to C₆ alkenyl, C₂ to C₈ cycloalkyl, phenyl, and thiophene;~~

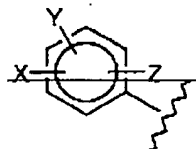
~~or R¹ and R² are fused to form a carbon-based 3 to 8 membered saturated spirocyclic ring;~~

~~— R³ is H;~~

~~R⁴ H;~~

~~R⁵ is selected from the group consisting of (i) and (ii):~~

~~(i) — a substituted benzene ring having the structure:~~



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~~X is selected from the group consisting of halogen, CN, C₁ to C₂ alkyl, substituted C₁ to C₃ alkyl, C₁ to C₂ alkoxy, NO₂, and C₁ to C₃ perfluoroalkyl;~~

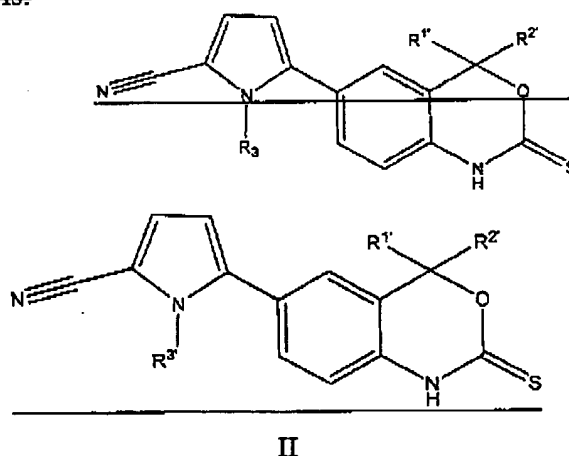
~~Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₃ alkoxy, C₁ to C₄ alkyl, and substituted C₁ to C₄ alkyl; and~~

~~(ii) a five or six membered carbon based heterocyclic ring having in its backbone 1 heteroatom selected from the group consisting of O, S, and NR⁶ and having one or two independent substituents selected from the group consisting of H, halogen, CN, C₁ to C₄ alkyl, and substituted C₁ to C₄ alkyl;~~

~~R⁶ is selected from the group consisting of H, C₁ to C₃ alkyl, and C₁ to C₄ CO₂alkyl;~~

~~Q⁺ is S;~~

~~and formula II is:~~



wherein:

R^{1'} is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

R^{2'} is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

R^{1'} and R^{2'} are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

~~R^{3'} is selected from the group consisting of C₁ to C₄ alkyl;~~

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of ~~formula I or~~ formula II.

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2(Currently Amended). The method according to claim 1, wherein said compound of ~~formula I or formula II~~ and said selective estrogen receptor modulator are delivered in a single composition.

3(Currently Amended). The method according to claim 1, wherein said compound of ~~formula I or formula II~~ and said selective estrogen receptor modulator are delivered separately.

4(Original). The method according to claim 1, wherein said selective estrogen receptor modulator is selected from the group consisting of EM-800, EM-652, raloxifene hydrochloride, arzoxifene, lasofoxifene, droloxifene, idoxifene, levormeloxifene, centchroman, nafoxidene, tamoxifen citrate, 4-hydroxytamoxifen citrate, clomiphene citrate, toremifene citrate, pipendoxifene, and bazedoxifene.

5(Original). The method according to claim 1, wherein said compound is delivered at a daily dosage of about 0.1 to about 50 mg.

6(Original). The method according to claim 1, wherein said regimen comprises delivering said composition daily for 1 to about 21 days, wherein said regimen is a cycle which is repeated monthly.

7(Currently Amended). ~~Then~~ The method according to claim 1, wherein said selective estrogen receptor modulator is delivered at a daily dosage of about 0.2 to about 100 mg.

8-24(Canceled).

25(Currently Amended). The method according to claim 1 wherein said compound of ~~formula I~~ is selected from the group consisting of ~~6-(3-Chlorophenyl)-4,4-~~

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~~dimethyl 1,4 dihydro benzo[d][1,3]oxazin-2-thione, 4 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H benzo[d][1,3]oxazin-6-yl) thiophene-2-carbonitrile, 3 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H benzo[d][1,3]oxazin-6-yl) 5-fluorobenzonitrile, 3 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H benzo[d][1,3]oxazin-6-yl) benzonitrile, 6 (3-fluorophenyl) 4-methyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 5 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 4-methylthiophene-2-carbonitrile, tert Butyl 2-cyano-5 (4,4 dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 1H-pyrrole-1-carboxylate, 5 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 1H-pyrrole-2-carbonitrile, [6 (4,4 dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) pyridin-2-yl]acetonitrile, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, 5 (4,4 dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 1H-pyrrole-2-carbenthiamide, 5 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H benzo[d][1,3]oxazin-6-yl) thiophene-3-carbonitrile, and 5-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-ethyl-1H-pyrrole-2-carbonitrile, 4-(1,2-Dihydro-2-thioxospiro[4H-3,1-benzoxazin-4,1-cyclohexan]-6-yl) 2-thiophenecarbonitrile, 5 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 2-fluorobenzonitrile, 6 (5-Bromopyridin-3-yl) 4,4 dimethyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 6 (3-Chloro-5-fluorophenyl) 4,4 dimethyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 6 (3-Bromo-5-methylphenyl) 4,4 dimethyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 6 (3-Bromo-5-trifluoromethoxyphenyl) 4,4 dimethyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 3 (1,2-Dihydro-2-thioxospiro[4H-3,1-benzoxazine-4,1-cyclohexan]-6-yl) 5-fluorobenzonitrile, 3 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 5-methylbenzonitrile, 6 (3,5-Dichlorophenyl) 4,4 dimethyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 5 (4,4 Dimethyl 1,2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) isophthalonitrile, 5 (4,4 Dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) 2-furenone, 4,4 Diethyl 6 (3-nitrophenyl) 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 6 (3-Chlorophenyl) 4-methyl 4-phenyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 4-Allyl-6 (3-chlorophenyl) 4-methyl 1,4 dihydro-2H-3,1 benzoxazine-2-thione, 3-Chloro-5 (4,4 dimethyl 2-thioxo 1,4 dihydro-2H-3,1 benzoxazin-6-yl) benzonitrile, 6 (3,5-~~

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~~Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Fluoro 5 methoxyphenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 5 methoxybenzonitrile, 6 (3 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Fluoro 5 (trifluoromethyl)phenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (2 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3,4 Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (4 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 4 fluorobenzonitrile, 6 (2,3 Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (8 Bromo 4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 5 fluorobenzonitrile, 4,4 Dimethyl 6 (3 nitrophenyl) 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Chlorophenyl) 4,4 diethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Methoxyphenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (2 Chlorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 4 Benzyl 6 (3 chlorophenyl) 4 methyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Bromo 5 fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 5 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) thiophene 2 carbonitrile, 3 Fluoro 5 (8 fluoro 4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl)benzonitrile, 3 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl)benzonitrile, 5 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl) 4 methyl 2 thiophenecarbonitrile, 5 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl) 2 thiophenecarbonitrile, 6 (3 Chloro 4 fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 5 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 4 propylthiophene 2 carbonitrile, 4 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 2 furonitrile, 4 Butyl 5 (4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl)thiophene 2 carbonitrile, 6 (3 Bromophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, and 2 (4,4 Dimethyl 2 thioxo 1,4~~

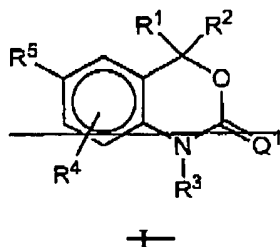
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~~dihydro-2H-3,1-benzoxazin-6-yl)thiophene-3-carbonitrile~~, or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug thereof.

26(Canceled).

27(Currently Amended). The method according to claim 414, wherein said compound of formula II is selected from the group consisting of: 5-(4-ethyl-4-methyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, 5-(4,4-diethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclobutan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclohexan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclopentan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-[2-thioxo-4,4-bis(trifluoromethyl)-1,4-dihydro-2H-3,1-benzoxazine-6-yl]-1H-pyrrole-2-carbonitrile, and prodrugs, metabolites, and pharmaceutically acceptable salts thereof.

28(Currently Amended). A pharmaceutical kit useful for inducing contraception, said kit comprising a compound of ~~formula I or~~ formula II and at least one selective estrogen receptor modulator, wherein ~~formula I is:~~



wherein:

~~R¹ and R² are independent substituents selected from the group consisting of H,~~
~~C₁-to-C₆ alkyl, substituted C₁-to-C₆ alkyl, C₂-to-C₆ alkenyl, C₂-to-C₂ cycloalkyl, phenyl,~~
~~and thiophene;~~

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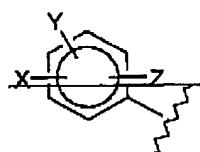
or R^1 and R^2 are fused to form a carbon based 3 to 8 membered saturated spirocyclic ring;

— R^3 is H;

— R^4 is H;

R^5 is selected from the group consisting of (i) and (ii):

(i) — a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, NO_2 , and C_1 to C_3 perfluoroalkyl;

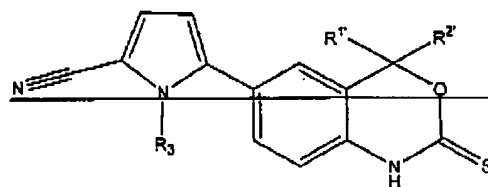
Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_3 alkoxy, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl; and

(ii) — a five or six membered carbon based heterocyclic ring having in its backbone 1 heteroatom selected from the group consisting of O, S, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl;

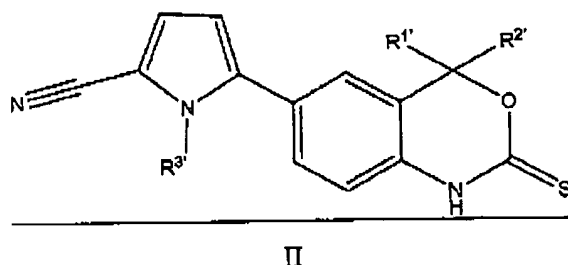
R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2 alkyl;

— Q^1 is S;

and formula II is:



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wherein:

R¹ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

R² is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

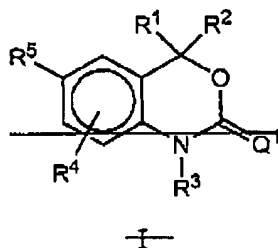
R¹ and R² are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

R³ is C₁ to C₄ alkyl;

and or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug thereof.

29(Currently Amended). A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or formula II, or a tautomer thereof, and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is:



wherein:

R¹ and R² are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₂ to C₆ alkenyl, substituted C₂ to C₆ alkenyl, C₂ to C₆ alkynyl, substituted C₂ to C₆ alkynyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A;

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or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;

a) — a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) — a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and

c) — a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

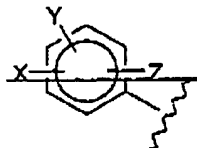
R^2 is selected from the group consisting of H, OH, NH_2 , C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C ;

R^6 is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;

R^4 is selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;

R^5 is selected from the group consisting of (i) and (ii):

(i) — a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3

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thioalkyl, substituted C_1 to C_2 thioalkyl, C_1 to C_2 aminoalkyl, substituted C_1 to C_2 aminoalkyl, NO_2 , C_1 to C_3 perfluoroalkyl, substituted C_1 to C_2 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D , $OCOR^D$, and $NR^E COR^D$;

R^D is selected from the group consisting of H, C_1 to C_2 alkyl, substituted C_1 to C_2 alkyl, aryl, substituted aryl, C_1 to C_2 alkoxy, substituted C_1 to C_2 alkoxy, C_1 to C_2 aminoalkyl, and substituted C_1 to C_2 aminoalkyl;

— R^E is selected from the group consisting of H, C_1 to C_2 alkyl, and substituted C_1 to C_2 alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_2 alkoxy, substituted C_1 to C_2 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_2 thioalkyl, and substituted C_1 to C_2 thioalkyl; and

(ii) — a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO_2 , and NR^F and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_2 alkoxy, substituted C_1 to C_2 alkoxy, C_1 to C_2 aminoalkyl, substituted C_1 to C_2 aminoalkyl, C_1 to C_2 perfluoroalkyl, substituted C_1 to C_2 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C_1 to C_2 thioalkyl, substituted C_1 to C_2 thioalkyl, COR^F , and $NR^G COR^F$;

R^F is selected from the group consisting of H, C_1 to C_2 alkyl, substituted C_1 to C_2 alkyl, aryl, substituted aryl, C_1 to C_2 alkoxy, substituted C_1 to C_2 alkoxy, C_1 to C_2 aminoalkyl, and substituted C_1 to C_2 aminoalkyl;

— R^G is selected from the group consisting of H, C_1 to C_2 alkyl, and substituted C_1 to C_2 alkyl;

R^G is selected from the group consisting of H, C_1 to C_2 alkyl, and C_1 to C_4 CO_2 alkyl;

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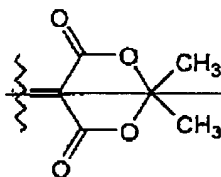
~~Q¹ is selected from the group consisting of S, NR⁷, and CR⁸R⁹;~~

~~R⁷ is selected from the group consisting of CN, C₁-to-C₆ alkyl, substituted C₁-to-C₆ alkyl, C₂-to-C₈ cycloalkyl, substituted C₂-to-C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO₂CF₃, OR¹¹, and NR¹¹R¹²;~~

~~R⁸ and R⁹ are independent substituents selected from the group consisting of H, C₁-to-C₆ alkyl, substituted C₁-to-C₆ alkyl, C₂-to-C₈ cycloalkyl, substituted C₂-to-C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO₂, CN, and CO₂R¹⁰;~~

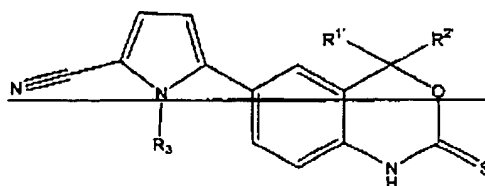
~~R¹⁰ is selected from the group consisting of C₁-to-C₂ alkyl and substituted C₁-to-C₂ alkyl;~~

~~or CR⁸R⁹ comprise a six membered ring having the structure:~~



~~R¹¹ and R¹² are independently selected from the group consisting of H, C₁-to-C₆ alkyl, substituted C₁-to-C₆ alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;~~

and formula II is:



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34(Currently Amended). The regimen according to claim 33, wherein said regimen comprises delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator for 14 to 24 days.

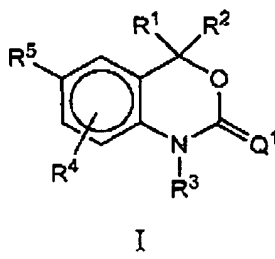
35(Currently Amended). The regimen according to claim 33, wherein said regimen comprises:

- (a) delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator for the first 14 to 24 days of said 28 day regimen; and
- (b) delivering said selective estrogen receptor modulator alone for 1 to 11 days beginning on any day between days 14 and 24.

36(Currently Amended). The regimen according to claim 35, wherein said regimen further comprises:

- (c) delivering a placebo for 1 to 10 days during the period of time where said compound of formula II and said selective estrogen receptor modulator are not delivered.

37(Currently Amended). The A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: according to claim 33



wherein:

R¹ and R² are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₂ to C₆ alkenyl, substituted C₂ to C₆ alkenyl, C₂ to C₆ alkynyl, substituted C₂ to C₆ alkynyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈

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cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms,
substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms,
COR^A, and NR^BCOR^A;

or R¹ and R² are fused to form a ring selected from the group consisting of a), b)
and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected
from the group consisting of H and C₁ to C₃ alkyl;

a) a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) a carbon-based 3 to 8 membered spirocyclic ring having one or more
carbon-carbon double bonds; and

c) a 3 to 8 membered spirocyclic ring having in its backbone one to three
heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃
alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, amino, C₁ to C₃
aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^B is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to
C₃ alkyl;

R³ is selected from the group consisting of H, OH, NH₂, C₁ to C₆ alkyl,
substituted C₁ to C₆ alkyl, C₃ to C₆ alkenyl, substituted C₃ to C₆ alkenyl, alkynyl,
substituted alkynyl, and COR^C;

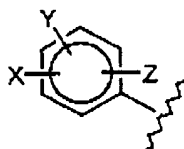
R^C is selected from the group consisting of H, C₁ to C₄ alkyl, substituted C₁ to C₄
alkyl, aryl, substituted aryl, C₁ to C₄ alkoxy, substituted C₁ to C₄ alkoxy, C₁ to C₄
aminoalkyl, and substituted C₁ to C₄ aminoalkyl;

R⁴ is selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₆ alkyl,
substituted C₁ to C₆ alkyl, C₁ to C₆ alkoxy, substituted C₁ to C₆ alkoxy, C₁ to C₆
aminoalkyl, and substituted C₁ to C₆ aminoalkyl;

R⁵ is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:

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X is selected from the group consisting of halogen, CN, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ thioalkyl, substituted C₁ to C₃ thioalkyl, C₁ to C₃ aminoalkyl, substituted C₁ to C₃ aminoalkyl, NO₂, C₁ to C₃ perfluoroalkyl, substituted C₁ to C₃ perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, OCOR^D, and NR^ECOR^D;

R^D is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^B is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, C₁ to C₃ thioalkyl, and substituted C₁ to C₃ thioalkyl; and

(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO₂, and NR^G and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, substituted C₁ to C₃ aminoalkyl, C₁ to C₃ perfluoroalkyl, substituted C₁ to C₃ perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C₁ to C₃ thioalkyl, substituted C₁ to C₃ thioalkyl, COR^F, and NR^GCOR^F;

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R^F is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^G is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl;

R⁶ is selected from the group consisting of H, C₁ to C₃ alkyl, and C₁ to C₄ CO₂alkyl;

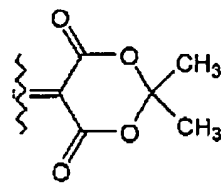
Q¹ is selected from the group consisting of S, NR⁷, and CR⁸R⁹;

R⁷ is selected from the group consisting of CN, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO₂CF₃, OR¹¹, and NR¹¹R¹²;

R⁸ and R⁹ are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO₂, CN, and CO₂R¹⁰;

R¹⁰ is selected from the group consisting of C₁ to C₃ alkyl and substituted C₁ to C₃ alkyl;

or CR⁸R⁹ comprise a six membered ring having the structure:

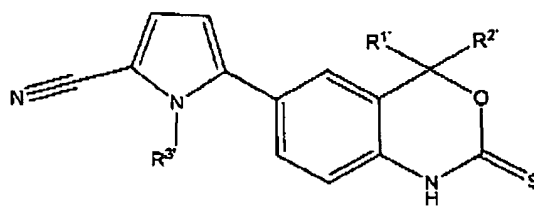


R¹¹ and R¹² are independently selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring

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having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



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wherein:

R^{1'} is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

R^{2'} is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

R^{1'} and R^{2'} are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

R^{3'} is C₁ to C₄ alkyl;

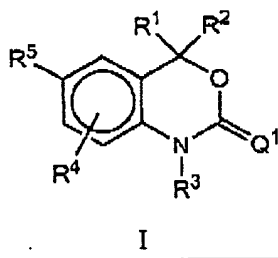
or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises:

(a) delivering said compound of formula I or formula II for the first 18 to 21 days of a 28 day regimen; and

(b) delivering said selective estrogen receptor modulator alone for 1 to 7 days following delivery of (a).

38(Currently Amended). The A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: according to claim 33

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wherein:

R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, C_2 to C_6 alkynyl, substituted C_2 to C_6 alkynyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A , and $NR^B COR^A$;

or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;

a) a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and

c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

R^3 is selected from the group consisting of H, OH, NH_2 , C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_6 alkenyl, substituted C_3 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C ;

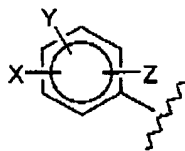
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R^C is selected from the group consisting of H, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, aryl, substituted aryl, C₁ to C₄ alkoxy, substituted C₁ to C₄ alkoxy, C₁ to C₄ aminoalkyl, and substituted C₁ to C₄ aminoalkyl;

R⁴ is selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₁ to C₆ alkoxy, substituted C₁ to C₆ alkoxy, C₁ to C₆ aminoalkyl, and substituted C₁ to C₆ aminoalkyl;

R⁵ is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ thioalkyl, substituted C₁ to C₃ thioalkyl, C₁ to C₃ aminoalkyl, substituted C₁ to C₃ aminoalkyl, NO₂, C₁ to C₃ perfluoroalkyl, substituted C₁ to C₃ perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, OCOR^D, and NR^ECOR^D;

R^D is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^E is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, C₁ to C₃ thioalkyl, and substituted C₁ to C₃ thioalkyl; and

(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO₂, and NR⁶ and having one or two independent substituents selected from the group consisting

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of H, halogen, CN, NO₂, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, substituted C₁ to C₃ aminoalkyl, C₁ to C₃ perfluoroalkyl, substituted C₁ to C₃ perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C₁ to C₃ thioalkyl, substituted C₁ to C₃ thioalkyl, COR^F, and NR^GCOR^F.

R^F is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^G is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl;

R⁶ is selected from the group consisting of H, C₁ to C₃ alkyl, and C₁ to C₄ CO₂alkyl;

Q¹ is selected from the group consisting of S, NR⁷, and CR⁸R⁹;

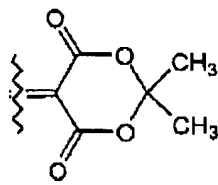
R⁷ is selected from the group consisting of CN, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO₂CF₃, OR¹¹, and NR¹¹R¹²;

R⁸ and R⁹ are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO₂, CN, and CO₂R¹⁰;

R¹⁰ is selected from the group consisting of C₁ to C₃ alkyl and substituted C₁ to C₃ alkyl;

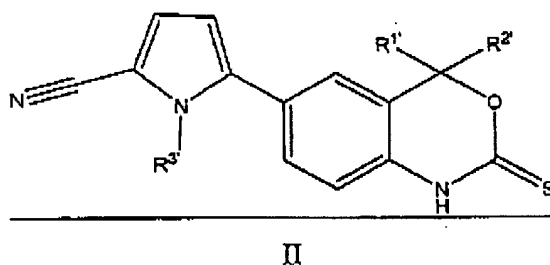
or CR⁸R⁹ comprise a six membered ring having the structure:

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R^{11} and R^{12} are independently selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

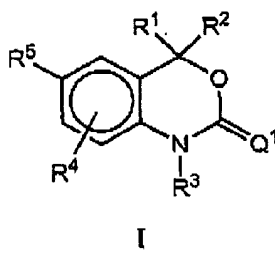
$R^{3'}$ is C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises:

- (a) delivering said compound of formula I or formula II and an estrogen for the first 21 days of a 28 day regimen; and
- (b) delivering said selective estrogen receptor modulator alone from days 22 to 24 of said 28 day regimen for 1 to 4 days.

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39(Currently Amended). ~~The method~~ A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: according to claim 29



wherein:

R¹ and R² are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₂ to C₆ alkenyl, substituted C₂ to C₆ alkenyl, C₂ to C₆ alkynyl, substituted C₂ to C₆ alkynyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A.

or R¹ and R² are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C₁ to C₃ alkyl:

- a) a carbon-based 3 to 8 membered saturated spirocyclic ring;
- b) a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and
- c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, amino, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl;

R^B is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl;

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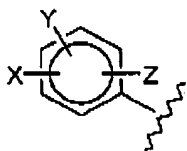
R^3 is selected from the group consisting of H, OH, NH_2 , C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_6 alkenyl, substituted C_3 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C ;

R^C is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;

R^4 is selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;

R^5 is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, NO_2 , C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D , $OCOR^D$, and $NR^E COR^D$;

R^D is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^E is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2 , C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 thioalkyl, and substituted C_1 to C_3 thioalkyl; and

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(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO₂, and NR⁶ and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO₂, C₁ to C₄ alkyl, substituted C₁ to C₄ alkyl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, substituted C₁ to C₃ aminoalkyl, C₁ to C₃ perfluoroalkyl, substituted C₁ to C₃ perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C₁ to C₃ thioalkyl, substituted C₁ to C₃ thioalkyl, COR^F, and NR^GCOR^F:

R^F is selected from the group consisting of H, C₁ to C₃ alkyl, substituted C₁ to C₃ alkyl, aryl, substituted aryl, C₁ to C₃ alkoxy, substituted C₁ to C₃ alkoxy, C₁ to C₃ aminoalkyl, and substituted C₁ to C₃ aminoalkyl:

R^G is selected from the group consisting of H, C₁ to C₃ alkyl, and substituted C₁ to C₃ alkyl:

R⁶ is selected from the group consisting of H, C₁ to C₃ alkyl, and C₁ to C₄ CO₂alkyl:

Q¹ is selected from the group consisting of S, NR⁷, and CR⁸R⁹:

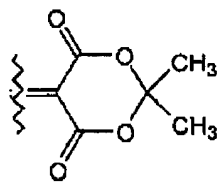
R⁷ is selected from the group consisting of CN, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO₂CF₃, OR¹¹, and NR¹¹R¹²:

R⁸ and R⁹ are independent substituents selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, C₃ to C₈ cycloalkyl, substituted C₃ to C₈ cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO₂, CN, and CO₂R¹⁰:

R¹⁰ is selected from the group consisting of C₁ to C₃ alkyl and substituted C₁ to C₃ alkyl:

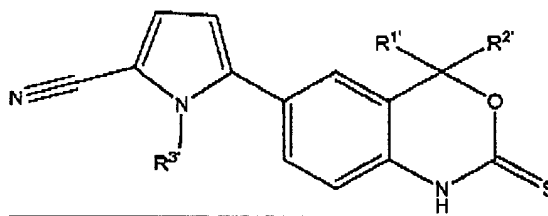
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or CR⁸R⁹ comprise a six membered ring having the structure:



R¹¹ and R¹² are independently selected from the group consisting of H, C₁ to C₆ alkyl, substituted C₁ to C₆ alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



II

wherein:

R¹ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

R² is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

R¹ and R² are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

R³ is C₁ to C₄ alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises 28 days and the steps of:

(a) a first phase of the compound of formula I or formula II and said selective estrogen receptor modulator to be administered on for the first days 14 to 24 days of said regimen;

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(b) a second phase of said selective estrogen receptor modulator to be administered ~~on days for~~ 1 to 11 days of said regimen beginning on any day between days 14 and 24; and

(c) a third phase of an orally and pharmaceutically acceptable placebo for ~~days 1 to 10 days of said regimen or a third phase in which component phase (a) or (b) is not administered for days 1 to 10 days of said regimen.~~

40(Currently Amended). The ~~method~~ regimen according to claim 39, wherein:

- (a) said first phase comprises 14 days;
- (b) said second phase comprises 7 days; and
- (c) said third phase comprises 7 days.